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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,246	02/08/2000	Todd P. Foster	6231.N-CN1	2305

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/500,246	FOSTER ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-28,32-38 and 42-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28,32-38 and 42-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 27 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 26 does not claim an embodiment in which the first and second delivery vehicles can contain mixtures of tablets and pellets, however, Claim 27 recites a mixture and, thus, is broader in scope than claim 26.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-28, 32-33, 36-38, 42-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amends the claims to indicate that the second delivery vehicle has large particle sizes. However, there is no indication in the Specification as to what would be considered a large particle size. The term "large" is a relative term which renders the claim indefinite. The term "large" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. If Applicant means that the particle size in the second delivery vehicle is larger than the particle size in the first delivery vehicle than the claim should clearly indicate the same.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cady et al. (US Pat. 6,498,153) in view of Okada et al. (US Pat. 4,652,441), Babcock et al. (US Pat. 3,417,182), Montgomery et al., and Grimm (US Pat. 5,522,797).

Cady et al. discloses first composition containing growth promoters, such as estradiol and/or trenbolone and a second composition containing said growth promoters and biodegradable polymer, each of said first and second compositions may contain starch, ethylcellulose, cllulose acetate, sucrose and polyvinylpyrrolidone (Columns 1-4). It is disclosed that the first composition is prepared by process comprising operations conventional in the pharmaceutical arts, for example the mixture of ingredients is granulated, screened and tableted into pellets (Column 7, lines 62-68, Column 8, lines 1,2). The second composition is formulated by mixing the ingredients, forming graulates, screening and tableting the granulate (Column 8, lines 3-11). It is disclosed that the compositions are administered parenterally, typically, subcutaneously as pellets to an inedible member of the animal, such as a cow, by means of a

syringe or pellet gun (Column 9, lines 13-25, Column 10, lines 5-17). It is disclosed that the uncoated pellets releases the growth promoter immediately whereas release of the coated pellet is delayed providing sustained release Column 7, lines 20-32, Column 9, lines 1-23).

Okada et al. discloses that disintegrating agents include starch (Column 9, lines 19-27).

Babcock et al. teach that melengesterol acetate is injectable and inplantable and useful in the veterinary field for control of estrual periods and stimulation of growth (See entire document, especially Abstract, Column 1, lines 41-45).

Montgomery et al. disclose that melengesterol acetate, trenbolone acetate and estradiol can be used together and that anabolic implants have been used as a production tool by cattle feeders for several decades (See entire reference, especially pages 1 and 4).

Grimm discloses a veterinary implanter for injecting a plurality of pellet doses, including approvide growth hormones, into the hide, skin or ears of an animal, such as cattle (Column 1, lines 5-14, 60-68, Column 4, lines 1-45). It is disclosed that the implanter avoids the problems of prior art implanters, failing to leave the pellets in the ear when withdrawing the needle or forgetting to advance the pellet magazine, by automatically advancing the pellet magazine and ejecting the pellets from the needle (Columns 1, 2).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose an implant composition consisting essentially of a first component comprising pellets of melengestrol acetate with disintegrating agent capable of immediately releasing the melengesterol and a second component comprising pellets of melengestrol acetate not containing a disintegrating agent which is capable of releasing on a sustained basis said melengestrol suitable for administration by a single injection consisting essentially of one to four

pellets of the first component and four to six pellets of type the second component and a method of delivering an implant containing the first claimed component and the second claimed component by injecting the inplant into the animal body. However, the prior art amply suggests the same as the prior art discloses implants containing hormones such as melengestrol acetate, trenbolone acetate and estradiol for increasing growth in animals, that said hormones can be used together and that hormone implants, such as pellets, can be injected into animals, and inplants with and without disintegrating agents, in the form of tablets or pellets, containing polymers, waxes, oils, fats or fatty acid esters, and that a plurality of inplants may be administered, and implants containing a first component in containing melengestrol acetate and disintegrating agent in a tablet for immediate release and melengestrol acetate without a disintegrating agent in a tablet for sustained release. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art with the expectation of increasing the growth of animals by injecting a plurality of devices as an inplant into the body of the animal, such as in the ear, which avoids a slow start up time by use of an immediately releasing component in combination with a sustained releasing component.

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC
January 14, 2005

SABIHA QAZI, PH.D
PRIMARY EXAMINER